

REMARKS

Claims 1-6, 8-17 and 19-40 are pending; claims 19-36 have been withdrawn from examination as being drawn to nonelected subject matter. Claims 1-6, 8-17 and 37-40 were rejected under 35 U.S.C. §112, first paragraph. Claims 37-40 were rejected under 35 U.S.C. §103(a).

Claims 37-40 have been canceled herein without prejudice or disclaimer of any previously claimed subject matter.

The amendments are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

On page 2 of the Office Action, the Examiner indicates that a Continued Prosecution Application under 37 CFR § 1.53(d) was filed, found acceptable and established. Applicants respectfully note that a Request for Continued Examination under 37 CFR § 1.114 was filed on August 18, 2002, not a Continued Prosecution Application.

Rejections under 35 U.S.C. §112, first paragraph

Claims 1-6, 8-17 and 37-40 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Applicants respectfully traverse this rejection.

As an initial matter, claims 37-40 have herein been canceled solely in the interest of expediting prosecution. Accordingly, the remarks below are in response to the rejection of claims 1-6 and 8-17.

In the rejection, the Examiner states that “the etiology of schizophrenia is not well-understood and treatment of the disease is generally limited to treating specific symptoms” and concludes that “the skilled artisan would be required to engage in undue experimentation to come up with a protocol that produces the intended effect.” Office Action, pages 3-4.

The claimed invention is directed to a method for providing dopamine or a dopamine precursor to a subject with schizophrenia through administering cells to the prefrontal cortex of the subject’s brain. The cells, which produce dopamine or a dopamine precursor, are administered adhered to a support matrix and in an amount effective to alleviate a negative symptom of schizophrenia.

Applicants respectfully submit that the specification provides all the required information for one of skill in the art to make and use the invention to alleviate a specific symptom of schizophrenia, a negative symptom. The specification teaches types of cells and types of support matrices appropriate for use in the claimed method. See, for example, pages 12-21. The specification teaches how to make the claimed cell support complex. See, for example, page 21, line 15, to page 22, line 6. The specification teaches administration of the claimed cell/support complex to the prefrontal cortex of a patient with schizophrenia. The specification provides guidelines as to site and means of administration of the complex and guidance as to the number of cells which produce dopamine or a dopamine precursor to be administered to the patient. See, for example, page 12, lines 1-6, and page 22, line 19, to page 23, line 11. The specification describes examples of negative symptoms of schizophrenia and standard methodology by which the symptoms may be assessed so that alleviation of a negative symptom can be determined. See, for example, page 7, line 21, to page 8, line 4, and page 23, lines 22-31.

As noted by the Examiner, Applicants have submitted evidence that, in patients with Parkinson’s disease, dopamine or dopamine precursor is effectively supplied to a region of the

brain through administration of cells adhered to a support matrix as described in the present invention. In addition, Davis et al. (1991, of record) teaches that increasing dopamine activity in the prefrontal cortex ameliorates symptoms associated with schizophrenia. See, for example p. 1479, right column, to p. 1480, right column.

The Examiner, however, states that “the level of dopamine expression required and attainable in PD patients is likely to be different than that required and attainable in schizophrenic patients, given that the etiology of these two diseases is different.” The Examiner also states that “it is unpredictable whether the causative process that leads to mesofrontal dopamine deficits will permit adequate replenishment of dopamine in the area of the brain or if it will continually destroy the newly available dopamine, thereby maintaining the dopamine deficit.” Office Action, page 5.

Applicants respectfully disagree with the Examiner’s statement and submit that there is no reason to expect that the level of dopamine expression attainable in a Parkinson’s disease patient is any different than that attainable in a patient with schizophrenia nor is there any support for the idea that dopamine is continually destroyed in the prefrontal cortex of the brain of a patient with schizophrenia. Applicants respectfully submit that the Examiner has not provided support for these statements which doubt the teachings of the specification and the art.

The specification provides guidance and direction to one skilled in the art to make and use the claimed invention. Applicants submit that the pending claims are in compliance with the enablement requirements.

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. §103

Claims 37-40 were rejected under 35 U.S.C. § 103 as allegedly obvious over U.S. Pat. No. 5,750,103 (Cherksey) and U.S. Pat. No. 5,942,437 (Sanberg et al.). Although Applicants

respectfully traverse this rejection, the interest of expediting prosecution, claim 37-40 have been canceled, rendering this rejection moot.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103.

CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 311772000600.

Respectfully submitted,

Dated: April 18, 2003

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